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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

8673 '00 MAR 29 A9:46

Johnson & Johnson Merck
Attn: George Latyszonek
Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, Pennsylvania 19034-2299

MAR 23 2000

Re: Docket No. 98N-0337
Comment No. APP7

Dear Mr. Latyszonek:

Reference is made to your Application for Exemption (AE) dated October 22, 1999, submitted under 21 CFR 201.66(e) for Pepcid AC Gelcaps (famotidine 10 mg) (NDA 20-902) in a sample pouch containing one gelcap, and your correspondence dated February 24, 2000.

Your AE requested exemption from several provisions of § 201.66: paragraphs (c)(8) (to exclude the inactive ingredients), (d)(10)(iii) to reduce the font size of the title and the headings, and (d)(8) and (d)(10)(v) to exclude barlines and hairlines. Your February 24, 2000 letter requested that your AE be converted to a request for deferral from the "Drug Facts" format requirements for a period of 9 months while the company acquires, implements, and validates the equipment necessary to produce compliant sample pouches. You stated that the sample pouches intended for distribution were designed and tested early in the product's development process, long before the May 16, 1999, effective date of the OTC labeling rule. You indicated that it is unrealistic to expect compliance for a product whose NDA approval was granted only 2 months after the rule's effective date.

You also included a proposed sample pouch which would be distributed during the deferral period. You stated that the sample pouch is identical to that included in your AE and reflects all of the text currently approved for use in Pepcid AC Gelcap labeling, with the exception that inactive ingredients are not listed.

For the reasons provided in your letter, the agency is converting your AE to a request for a deferral from the "Drug Facts" labeling format requirements. The agency is granting a period of 9 months from the date of this letter for the labeling of this product to comply with the requirements of 21 CFR 201.66.

During the deferral period, you may distribute a sample pouch that contains the text of the currently approved labeling for Pepcid AC Gelcaps in the "Drug Facts" format in your AE request (without the inactive ingredients listed). However, you must remove the "Drug Facts" and "Drug

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Facts (continued)" titles from the labeling because including this information would give the impression that the agency approved "Drug Facts" labeling that does not contain all of the required information and that is not in the correct format. If you distribute these pouches to consumers with any printed material during the deferral period, please consider including the inactive ingredients in the printed material.

If you have not already done so, you should submit a supplement to your NDA requesting approval of the labeling to be used during the deferral period. We will make every effort to respond to that supplement as quickly as possible.

Should you have any questions, please contact Elizabeth F. Yuan, R.Ph., Regulatory Project Manager, at (301) 827-2222.

Sincerely yours,

Charles J. Ganley, M.D,
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE:

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 98N-0357

TO: Dockets Management Branch, HFA-305

☒ The attached material should be placed on public display under the above referenced Docket No.

☐ This material should be cross-referenced to Comment No. App 7 ; 8

Charles J. Ganley, M.D.

Attachment